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**UNITED STATES DISTRICT COURT**
**DISTRICT OF NEW JERSEY**

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| BRIAN FELDMAN, Individually and On Behalf of All Others Similarly Situated,<br><br>Plaintiff,<br><br>v.<br><br>SCYNEXIS, INC, DAVID ANGULO, AND IVOR MACLEOD,<br><br>Defendants. | Case No. 23-cv-22082-BRM-CLW<br><br>**AMENDED CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS**<br><br>**JURY TRIAL DEMANDED** |

Lead Plaintiff Brian Feldman ("Plaintiff"), individually and on behalf of all others similarly situated, by and through his attorneys, alleges the following upon information and belief, except as to those allegations concerning Plaintiff, which are alleged upon personal knowledge. Plaintiff's information and belief is based upon, among other things, his counsel's investigation, which includes without limitation: (a) review and analysis of regulatory filings made by SCYNEXIS, Inc. ("Scynexis" or the "Company") with the United States ("U.S.") Securities and Exchange Commission ("SEC"); (b) review and analysis of press releases and media reports issued by and disseminated by Scynexis; and (c) review of other publicly available information concerning Scynexis.

## I. NATURE OF THE ACTION AND OVERVIEW

1. This is a class action on behalf of persons and entities that purchased or otherwise acquired Scynexis securities between March 31, 2023 and September 22, 2023, inclusive (the "Class Period"). Plaintiff pursues claims against Defendants under the Securities Exchange Act of 1934 (the "Exchange Act").

2. Scynexis is a biotechnology company primarily engaged in the development of ibrexafungerp, a broad-spectrum agent for fungal indications that is administered intravenously ("IV") or orally.

3. In June 2021, the Company received approval from the United States Food and Drug Administration ("FDA") for the use of ibrexafungerp tablets,

distributed under the brand name BREXAFEMME® for the treatment of vulvovaginal candidiasis (also known as vaginal yeast infection). Soon thereafter, the Company announced that the product had been manufactured, packaged, and distributed to pharmacies.

4. The FDA ensures the quality of drug products, such as ibrexafungerp, by promulgating its current Good Manufacturing Practice ("cGMP") regulations. These regulations for drugs contain minimum requirements for the methods, facilities, and controls used in manufacturing, processing, and packing of a drug product that ensure a product is safe for use and has the ingredients and strength it claims to have.

5. Beta-lactams (or ß-lactam) are a class of chemical compounds used in the production of certain drugs.[1] All beta-lactams, including non-antibacterial beta-lactam, can be sensitizing agents, meaning their presence can cause an allergic reaction. Hypersensitivity to beta-lactams is among the most commonly reported drug allergies. The threshold for an allergic response to a beta-lactam is extremely low and difficult to detect; even a small amount can cause a serious and life-threatening reaction. Even without an allergy, the interaction between a beta-lactam

[1] Penicillin, for example, is a beta-lactam.

and other chemicals can induce hypersensitivity and a potentially life-threatening response.

6. Because of the serious and life-threatening potential to cause allergic responses, FDA guidelines and regulations involve special precautions to reduce the risk of cross-contamination from beta-lactams. Indeed, cGMP requires that the manufacture of non-antibacterial beta-lactam compounds are segregated from other compounds to reduce potential hypersensitivity reactions. These regulations are clear and must be followed. The FDA guidelines' specifically state the ***"[p]rocessing of beta-lactam drugs without complete and comprehensive separation from non-beta-lactam products is an example of an insanitary condition*** that FDA has observed."[2]

7. On March 30, 2023, the Company entered into a license agreement with GSK plc ("GSK"), formerly known as GlaxoSmithKline, for an exclusive, royalty-bearing license for the development, manufacture, and commercialization of ibrexafungerp, including the approved product BREXAFEMME, for all indications. Under the license agreement, the Company would receive an upfront payment of $90 million and potential payments if certain milestones were met. In total, the

[2] All emphasis is added unless otherwise stated.

Company was eligible to receive $503 million milestone-based payments, as well as royalties based on cumulative annual sales.

8. Less than six months later, on September 25, 2023, the Company disclosed that GSK had uncovered potential cross contamination of ibrexafungerp with a non-antibacterial beta-lactam drug substance. The Company therefore declared it would conduct a recall of BREXAFEMME from the market and place a temporary hold on clinical studies of ibrexafungerp, including a Phase 3 clinical study, until a mitigation strategy and a resupply plan were determined.

9. On this news, the Company's shares fell $1.13, or 34.14%, to close at $2.18 per share on September 25, 2023, on unusually heavy trading volume. The stock price continued to decline the next trading day by 11.47% to close at $1.93 per share on September 26, 2023, on unusually heavy trading volume.

10. Analysts were surprised that clear FDA guidelines had not been followed. For example, an analyst from Ladenburg Thalmann wrote in a report to shareholders in the months after the disclosure:

> ***We still lack clarity as to why the manufacturing equipment was shared with beta-lactams and how it was not discovered earlier.*** Recall, Brexafemme earned FDA approval for vulvovaginal yeast infections in June 2021, and we believe its commercial manufacturing is the same as its clinical manufacturer. ***We would expect that ahead of GSK's March licensing agreement it would have physically inspected the IBX manufacturing facilities***.

11. Throughout the Class Period, Defendants made materially false and/or misleading statements, as well as failed to disclose material adverse facts about the Company's business, operations, and prospects. Specifically, Defendants failed to disclose to investors: (1) that the equipment used to manufacture ibrexafungerp was not sufficiently separated from the manufacture of a non-antibacterial beta-lactam drug substance, presenting a risk of cross-contamination; (2) that the Company did not ensure compliance with current Good Manufacturing Practices ("cGMP"); and (3) that, due to the failure to ensure the manufacture of ibrexafungerp was separated from the manufacture of non-antibacterial beta-lactam drugs, there were undisclosed material risks to the Company's business, including risks related to potential recalls and delays in clinical studies.

12. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages.

## II. JURISDICTION AND VENUE

13. The claims asserted herein arise under Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. § 240.10b-5).

14. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and Section 27 of the Exchange Act (15 U.S.C. § 78aa).

15. Venue is proper in this Judicial District pursuant to 28 U.S.C. § 1391(b) and Section 27 of the Exchange Act (15 U.S.C. § 78aa(c)). Substantial acts in furtherance of the alleged fraud or the effects of the fraud have occurred in this Judicial District. Many of the acts charged herein, including the dissemination of materially false and/or misleading information, occurred in substantial part in this Judicial District.

16. In connection with the acts, transactions, and conduct alleged below, Defendants directly and indirectly used the means and instrumentalities of interstate commerce, including the United States mail, interstate telephone communications, and the facilities of a national securities exchange.

## III. PARTIES

17. Lead Plaintiff Brian Feldman, as set forth in certification previously filed with the Court, incorporated by reference herein, purchased Scynexis securities during the Class Period, and suffered damages as a result of the federal securities law violations and false and/or misleading statements and/or material omissions alleged.

18. Defendant Scynexis is incorporated under the laws of the Delaware with its principal executive offices located in Jersey City, New Jersey. Scynexis trades on the NASDAQ exchange under the symbol "SCYX."

19. Defendant David Angulo ("Angulo") has been the President Chief Executive Officer ("CEO") and a Board Member of Scynexis since January 2023. Defendant Angulo, who according to the Company is an infectious disease specialist with more than 20 years of experience in successful drug development, joined SCYNEXIS in 2015 as Chief Medical Officer. Before joining Scynexis, Angulo served as Vice President, Research and Development of Brickell Biotech, Inc. and before that, held various senior positions at Stiefel Laboratories, Inc., a GSK company, including head of the clinical and medical departments. Angulo has also been responsible for several development programs in the anti-infectives area at Schering-Plough Research Institute and was an infectious disease physician in a pediatric hospital. He received his medical degree from the Universidad de Guadalajara, Mexico, and has post-graduate degrees in pediatrics and infectious diseases.

20. Defendant Ivor Macleod ("Macleod") has been the Chief Financial Officer ("CFO") of Scynexis since October 2022. According to the Company, Macleod is a senior pharmaceutical executive with more than 30 years of financial and operational experience in the life sciences industry. Before joining Scynexis, Macloed had served as CFO of Athersys, Inc. since 2020. From 2015 to 2018, he served as the Chief Financial Officer and Chief Compliance Officer of Eisai Inc., the U.S. pharmaceutical subsidiary of Eisai Co., Ltd., a Japanese research-based

human health care company that discovers, develops and markets products globally. Before joining Eisai Inc., Macleod served as the Vice President of Finance in the Merck Research Labs at Merck & Co., Inc., a global healthcare company that delivers health solutions through its prescription medicines, vaccines, biologic therapies and animal health products, from 2012 to 2015. And before joining Merck, Macleod served from 1998 to 2012 at F. Hoffmann-La Roche, Inc., a multinational health care company, in various roles, including as North American Chief Financial Officer from 2000 to 2011 as well as General Manager from 2010 to 2011. Macleod received his B.Sc. from St. Andrews University in Scotland and his M.B.A. from the University of Arizona, and is a Certified Public Accountant licensed in Virginia.

21. Defendants Angulo and Macleod (together, the "Individual Defendants"), because of their positions with the Company, possessed the power and authority to control the contents of the Company's reports to the SEC, press releases and presentations to securities analysts, money and portfolio managers and institutional investors, i.e., the market. The Individual Defendants were provided with copies of the Company's reports and press releases alleged herein to be misleading prior to, or shortly after, their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of their positions and access to material nonpublic information available to them, the Individual Defendants knew that the adverse facts specified herein had not been

disclosed to, and were being concealed from, the public, and that the positive representations which were being made were then materially false and/or misleading. The Individual Defendants are liable for the false statements pleaded herein.

## IV. SUBSTANTIVE ALLEGATIONS

22. Scynexis is a biotechnology company originally founded in 1999. Currently, the company is primarily engaged in the development of ibrexafungerp, a broad-spectrum agent for multiple fungal indications.

### A. The FDA's Current Good Manufacturing Practice Requirements

23. The FDA ensures the quality of drug products by carefully monitoring drug manufacturers' compliance with its cGMP regulations in order to make sure that a product is safe to use and that it has the ingredients and strength it claims to have.

24. Specifically, Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351(a)(2)(B)) requires that, with few exceptions, all drugs be manufactured in compliance with the cGMP regulations. Drugs that are not in compliance with cGMPs are considered to be adulterated and may not be introduced or delivered into interstate commerce. *See* 21 U.S.C. § 351(a)(2)(B); 21 U.S.C. § 331(a). The cGMPs concern, among other things, the manufacturing of drugs (21

C.F.R. § 210); finished pharmaceuticals (21 C.F.R. § 211); and biological products (21 C.F.R. § 600).

25. The approval process for new and generic drug marketing applications includes the FDA's review of the manufacturer's compliance with cGMP. FDA assessors and investigators determine whether the firm has the necessary facilities, equipment, and ability to manufacture the drug it intends to market.

**1. Scynexis Must Prevent Cross-Contamination**

26. The cGMP set out at 21 C.F.R. § 211.42(c) requires building and facility controls to prevent cross-contamination of drug products.

27. Drug cross contamination can be deadly; for example, penicillin can be a sensitizing agent that triggers a hypersensitive exaggerated allergic immune response in some people. Accordingly, the FDA requires implementing methods for preventing cross contamination of other drugs with penicillin, including that the "manufacture, processing, and packing of penicillin shall be performed in facilities separate from those used for other drug products for human use." 21 C.F.R. §§ 211.42(d).

28. Non-penicillin beta-lactam drugs can also act as sensitizing agents and cross-contamination can initiate the same types of drug-induced hypersensitivity reactions, including life-threatening allergic reactions. Therefore, the FDA has

promulgated guidance[3] entitled "Non-Penicillin Beta-Lactam Drugs: A CGMP Framework for Preventing Cross-Contamination" which describes the importance of implementing controls to prevent cross-contamination of pharmaceuticals with non-penicillin beta-lactam drugs. FDA-2011-D-0104 (April 17, 2013).[4]

29. The FDA's Non-Penicillin Beta-Lactam cGMP states the FDA expects the separation in manufacturing and production of all classes of beta-lactam drugs. The guidance states "[j]ust as FDA considers the separation of production facilities for penicillins to be current good manufacturing practice, [the] FDA expects manufacturers to treat sensitizing non-penicillin beta-lactam-based products similarly." Accordingly, the FDA recommends that the area in which any class of sensitizing beta-lactam is manufactured should be "***completely and comprehensively separated***" from areas in which any other products are manufactured. The guidance further recommends that firms which manufacture beta-lactam, receive them for further processing, or ***whose manufacturing processes result in beta-lactam derivatives***, should ***evaluate their manufacturing operations***

[3] A copy of the FDA's guidance is publicly available at https://www.fda.gov/files/drugs/published/Non-Penicillin-Beta-Lactam-Drugs--A-CGMP-Framework-for-Preventing-Cross-Contamination.pdf

[4] Guidance documents describe the FDA's interpretation of our policy on a regulatory issue (21 CFR 10.115(b)).

***for the possibility of cross-contamination*** and ***implement appropriate controls to reduce or mitigate the potential for cross-contamination***.

30. Therefore, Scynexis is required to separate beta-lactam products and must ensure that third-party manufacturers do so, too. *See* FDA-2013-D-0558 (Nov. 23, 2016) ("both owners and contract facilities that conduct manufacturing operations" are "responsible for ensuring compliance with CGMP").

**2. Scynexis Must Prevent Insanitary Conditions**

31. Section 501(a)(2)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351(a)(2)(A)) provides that a drug is adulterated "if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health." Drug products prepared, packed, or held under insanitary conditions could become contaminated and cause serious adverse events, including death.

32. The FDA's guidance for industry on "Insanitary Conditions at Compounding Facilities" explains that "***[p]rocessing of beta-lactams without complete and comprehensive separation from non-beta-lactam products***" is an example of an ***insanitary condition***. FDA-2016-D-2268 (Nov. 6, 2020).

33. Similarly, the FDA's guidance for industry on "Compounding Certain Beta-Lactam Products in Shortage Under Section 503A of the Federal Food Drug and Cosmetic Act" reiterates that the ***"[p]rocessing of beta-lactam drugs without***

***complete and comprehensive separation from non-beta-lactam products is an example of an insanitary condition*** that FDA has observed." FDA-2022-D-2922 (Nov. 11, 2022).

### B. Since The Sale Of BREXAFEMME For Its Approved Treatment Was Not Sufficiently Profitable, Scynexis Pivoted In A New Direction With A New Executive Team

34. In June 2021, the Company received approval from the FDA for a New Drug Application for BREXAFEMME for the treatment of vulvovaginal candidiasis (also known as vaginal yeast infection).[5]

35. According to the Company's fiscal 2021 annual report, by August 2021 the product had been manufactured, packaged, and distributed to pharmacies. Scynexis had agreements with contract manufacturers and external vendors to produce the drug product and drug substance for ongoing clinical trials and for commercial product. The Company further explained that it believed its team was capable of overseeing the manufacturing process and ensuring its third-party vendors were complying with compliance requirements:

> A drug manufacturing program subject to extensive governmental regulations requires robust quality assurance systems and experienced personnel with the relevant technical and regulatory expertise as well as strong project management skills. We believe we have a team that is capable of managing these activities.

[5] In December of 2022, after the Company pivoted away from BREXAFEMME, it received FDA approval for an additional indication of recurrent vulvovaginal candidiasis.

> The primary third-party vendors with which we have agreements in place to support manufacturing and supply both for clinical development and commercial launch have the required capabilities with respect to facilities, equipment and technical expertise, quality systems that meet global regulatory and compliance requirements, satisfactory regulatory inspection history from relevant health authorities and proven track records in supplying drug substance and drug product for late-stage clinical and commercial use.

36. After the Company brought BREXAFEMME, its sole drug candidate, to market, it was not profitable in the least. As the Company admitted in its March 31, 2023 Annual Report issued at the beginning of the Class Period:

> We are not profitable and do not expect to be profitable in the foreseeable future. We have incurred net losses in each year since our inception, including a net loss of $62.8 million for the year ended December 31, 2022. As of December 31, 2022, we had an accumulated deficit of approximately $422.3 million.

37. As a result, Scynexis sought to develop alternative revenue streams. In October 2022, the Company announced a new strategic direction to refocus its resources on the clinical development of ibrexafungerp for severe, hospital-based indications, where higher long-term returns are expected. According to the Company, in connection with this new strategic direction, Scynexis intended to out-license BREXAFEMME for vaginal yeast infections and was actively pursuing a U.S. commercialization partner. Moreover, the Company announced that it would wind down its promotional activities for BREXAFEMME, while keeping BREXAFEMME on the market and available to patients.

38. Along with these changes to its business strategy, the Company announced that its CEO, President and Board Member, Dr. Marco Taglietti, would retire and be replaced by then-Chief Medical Officer, Defendant Angulo. Moreover, the Company announced that it had fired its Chief Commercial Officer, Christine Coyne, and Interim Chief Financing Officer, Larry Hoffman. Additionally, the Company announced that Ivor Macleod would become the new CFO.

39. Scynexis found its commercialization partner in GSK. On March 30, 2023, the Company entered into a license agreement with GSK for an exclusive, royalty-bearing license for the development, manufacture, and commercialization of ibrexafungerp, including the approved product BREXAFEMME, for all indications, in all countries other than Greater China and certain other countries. The Company would receive an upfront payment of $90 million and potential payments if certain milestones were met, including regulatory approval milestone payments of up to $70 million, commercial milestone payments of up to $115 million, and sales milestone payments of up to $242.5 million based on annual net sales. In total, the Company was eligible to receive potential milestone-based payments totaling $503 million in addition to royalties based on a percentage of cumulative annual sales (which would be in the mid-single digit to mid-teen range).

40. On June 21, 2023, the Company announced the achievement of a $25 million performance-based development milestone under the GSK license agreement.

### C. The Company's New Commercialization Partner Quickly Uncovers That Scynexis Was Not Complying With Current Good Manufacturing Practices, Resulting In A Recall And The Cratering Of The Company's Stock

41. On September 25, 2023, before the market opened, Scynexis announced it would voluntarily recall BREXAFEMME, tablets, due to risk of cross contamination. On that date, the Company filed a Form 8-K report, stating:

> Following a recent review by GSK of the manufacturing process and equipment at the vendor that manufactures the ibrexafungerp drug substance, ***SCYNEXIS became aware that a non-antibacterial beta-lactam drug substance is manufactured using equipment common to the manufacturing process for ibrexafungerp.*** Current FDA guidance recommends segregating the manufacture of beta-lactam compounds from other compounds since beta-lactam compounds have the potential to act as sensitizing agents that may trigger hypersensitivity or an allergic reaction in some people. In the absence of the recommended segregation, there is a risk of cross contamination. It is not known whether any ibrexafungerp has been contaminated with a beta-lactam compound and SCYNEXIS has not received reports of adverse events established to be due to the possible beta-lactam cross contamination. Nonetheless, in light of this risk and out of an abundance of caution (and aligned with GSK's recommendation), ***SCYNEXIS is recalling BREXAFEMME® (ibrexafungerp tablets) from the market and placing a temporary hold on clinical studies of ibrexafungerp, including the Phase 3 MARIO study, until a mitigation strategy and a resupply plan are determined.***

42. On this news, the Company's shares fell $1.13, or 34.14%, to close at $2.18 per share on September 25, 2023, on unusually heavy trading volume. The

stock price continued to fall the next trading session by 11.47% to close at $1.93 per share on September 26, 2023, also on unusually heavy trading volume.

43. On September 27, 2023, Scynexis issued a press release announcing the voluntary nationwide recall of 2 lots of BREXAFEMME. As the Company explained: "During a review of manufacturing equipment and cleaning activities at a supplier, SCYNEXIS was made aware of potential cross-contamination risk with a non-antibacterial beta-lactam drug substance."

44. According to the Company's third quarter 2023 Quarterly Report filed with the SEC on November 11, 2023, Scynexis began engaging with the FDA in September 2023 and "the FDA concurred with the Company's voluntary hold and placed a clinical hold on ibrexafungerp." Further, the Company disclosed that the "clinical hold and recall create uncertainty as to the timing of achieving, and the Company's ability to achieve, the milestones under the license agreement with GSK."

45. On January 1, 2024, the Company disclosed that it had agreed to revise the terms of license agreement with GSK because of the delays in commercialization and clinical development of BREXAFEMME caused by the recall and temporary hold on clinical studies. Under the terms of the revised agreement, Scynexis's potential payments were substantially reduced. For example, the Company's potential regulatory approval milestone payments were reduced from $70 million to

$49 million, commercial milestone payments were reduced from up to $115 million to up to $57.5, and sales milestone payments of up to $242.5 million were reduced to as little as $145.5 million (depending on the date of GSK's relaunch of BREXAFEMME in the U.S.).

46. According to the Company's annual report filed with the SEC on March 26, 2024, Scynexis had engaged new manufacturers and vendors. Specifically, it stated:

> in response to the hold on clinical studies of ibrexafungerp by the FDA due to possible beta-lactam cross contamination, [the Company has] entered into certain new manufacturing agreements with third-party contract manufacturers to begin producing new batches of ibrexafungerp which we believe will allow us to lift the clinical hold and restart our impacted clinical studies, the Phase 3 MARIO study and a Phase 1 lactation study.

## V. MATERIALLY FALSE AND MISLEADING STATEMENTS AND OMISSIONS ISSUED DURING THE CLASS PERIOD

47. The Class Period begins on March 31, 2023. On that day, Scynexis filed a Form 10-K for the period ended December 31, 2022 (the "2022 10-K"). The 2022 10-K claimed that the Company's vendors for the "manufacturing and supply both for clinical development and commercial needs ***have the required capabilities with respect to facilities, equipment and technical expertise, quality systems that meet global regulatory and compliance requirements***." Specifically, the 2022 10-K reported, in relevant part:

**Manufacturing and Supply of Ibrexafungerp**

> We have agreements with external vendors that are capable of supplying drug substance and of producing drug product to support ongoing and planned clinical trials, as well as for commercial product. However, we do not own or operate and do not intend to own or operate facilities for manufacturing, storage and distribution, or testing of drug substance or drug product.
>
> * * *
>
> A drug manufacturing program subject to extensive governmental regulations requires robust quality assurance systems and experienced personnel with the relevant technical and regulatory expertise as well as strong project management skills. ***We believe we have a team that is capable of managing these activities until GSK assumes responsibility for them pursuant to the License Agreement***.
>
> ***The primary third-party vendors with which we have agreements in place to support manufacturing and supply both for clinical development and commercial needs have the required capabilities with respect to facilities, equipment and technical expertise, quality systems that meet global regulatory and compliance requirements, satisfactory regulatory inspection history from relevant health authorities and proven track records in supplying drug substance and drug product for late-stage clinical and commercial use***.

48. The 2022 10-K further purported to warn that the Company "may" be held responsible for the contract manufacturers' failure to comply with cGMP and that the failure to comply with cGMP "can" have legal implications. Specifically, the 2022 10-K stated, in relevant part:

> BREXAFEMME, ibrexafungerp, and any other future product candidates we may seek to develop will also be subject to ongoing regulatory requirements for the packaging, storage, advertising, promotion, record-keeping and submission of safety and other post-market information on the drug. In addition, approved products, manufacturers and manufacturers' facilities are required to comply with extensive FDA requirements, including ensuring that quality control and manufacturing procedures conform to current Good Manufacturing

> Practices (cGMP). As such, we and our contract manufacturers, which we will be responsible for overseeing and monitoring for compliance, are subject to continual review and periodic inspections to assess compliance with cGMP. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control. ***The FDA may hold us responsible for any deficiencies or noncompliance of our contract manufacturers in relation to ibrexafungerp and any other future product candidates we may seek to develop. Failure to follow cGMP can result in products being deemed adulterated, which carries significant legal implications.***

49. On May 1, 2023, the Company filed a Form ARS with the SEC, which reported the Company's Annual Report to Security Holders. The report reiterated the statements from the Company's 10-K, including that the Company's vendors for the "manufacturing and supply both for clinical development and commercial needs ***have the required capabilities with respect to facilities, equipment and technical expertise, quality systems that meet global regulatory and compliance requirements***." Specifically, the report stated, in relevant part:

> **Manufacturing and Supply of Ibrexafungerp**
>
> We have agreements with external vendors that are capable of supplying drug substance and of producing drug product to support ongoing and planned clinical trials, as well as for commercial product.
>
> * * *
>
> A drug manufacturing program subject to extensive governmental regulations requires robust quality assurance systems and experienced personnel with the relevant technical and regulatory expertise as well as strong project management skills. ***We believe we have a team that is capable of managing these activities until GSK assumes responsibility for them pursuant to the License Agreement.***

> ***The primary third-party vendors with which we have agreements in place to support manufacturing and supply both for clinical development and commercial needs have the required capabilities with respect to facilities, equipment and technical expertise, quality systems that meet global regulatory and compliance requirements***, satisfactory regulatory inspection history from relevant health authorities and proven track records in supplying drug substance and drug product for late-stage clinical and commercial use.

50. The May 1, 2023 report further purported to warn that the Company "may" be held responsible for the contract manufacturers' failure to comply with cGMP, stating in relevant part:

> BREXAFEMME, ibrexafungerp, and any other future product candidates we may seek to develop will also be subject to ongoing regulatory requirements for the packaging, storage, advertising, promotion, record-keeping and submission of safety and other post-market information on the drug. In addition, approved products, manufacturers and manufacturers' facilities are required to comply with extensive FDA requirements, including ensuring that quality control and manufacturing procedures conform to current Good Manufacturing Practices (cGMP). As such, we and our contract manufacturers, which we will be responsible for overseeing and monitoring for compliance, are subject to continual review and periodic inspections to assess compliance with cGMP. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control. ***The FDA may hold us responsible for any deficiencies or noncompliance of our contract manufacturers in relation to ibrexafungerp and any other future product candidates we may seek to develop. Failure to follow cGMP can result in products being deemed adulterated, which carries significant legal implications.***

51. The above statements identified in ¶¶ 47-50 were materially false and/or misleading, and failed to disclose material adverse facts about the Company's business, operations, and prospects. Specifically, Defendants failed to disclose to

investors: (1) that the equipment used to manufacture ibrexafungerp was not sufficiently separated from the manufacture of a non-antibacterial beta-lactam drug substance, presenting a risk of cross-contamination; (2) that the Company did not ensure compliance with current Good Manufacturing Practices (cGMP); and (3) that, due to the failure to ensure the manufacture of ibrexafungerp was separated from the manufacture of non-antibacterial beta-lactam drugs, there were undisclosed material risks to the Company's business, including risks related to potential recalls and delays in clinical studies.

## VI. LOSS CAUSATION

52. Defendants' wrongful conduct, as alleged, directly and proximately caused the economic loss suffered by Plaintiff and the Class. Defendants' misrepresentations and omissions caused and maintained the artificial inflation in the Company's stock price throughout the Class Period.

53. On September 25, 2023, before the market opened, Scynexis announced it would voluntarily recall BREXAFEMME tablets due to risk of cross contamination, admitting that the facilities did not comply with cGMP. On this news, the Company's shares fell $1.13, or 34.14%, to close at $2.18 per share on September 25, 2023, on unusually heavy trading volume. The stock price continued to fall the next trading session by 11.47% to close at $1.93 per share on September 26, 2023, also on unusually heavy trading volume.

54. During the Class Period, Plaintiff and the Class purchased the Company's securities at artificially inflated prices and were damaged thereby. The price of the Company's securities plummeted when the misrepresentations made to the market, and/or the information alleged herein to have been concealed from the market, and/or the effects thereof, were revealed, causing investors' losses.

## VII. ADDITIONAL SCIENTER ALLEGATIONS

55. As alleged here, Defendants acted with scienter because they knew that the public documents and statements issued or disseminated in the name of Scynexis were materially false and/or misleading; knew that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the federal securities laws.

56. As alleged here, the Individual Defendants, by virtue of their receipt of information reflecting the true facts regarding Scynexis, their control over, and/or receipt and/or modification of Scynexis's allegedly materially misleading misstatements and/or their associations with Scynexis which made them privy to confidential proprietary information concerning Scynexis, participated in the fraudulent scheme alleged here.

### A. The Company's Compliance With FDA Guidelines Was Central To Its Business

57. Scynexis is an extremely small company: as of March 1, 2023, it had only 36 full-time employees. Moreover, Scynexis has a singular drug candidate, ibrexafungerp. Its primary business was the commercialization of ibrexafungerp, and it derived revenue from the sale of BREXAFEMME and the development of ibrexafungerp for new indications with GSK. Therefore, the integrity of ibrexafungerp was critical to the Company's business.

58. As such, it is inconceivable that its employees would not be aware of the FDA's guidance on manufacturing anti-fungal drugs. Here, the FDA's guidance for industry on "Insanitary Conditions at Compounding Facilities" explains that "***[p]rocessing of beta-lactams without complete and comprehensive separation from non-beta-lactam products***" is an example of an ***insanitary condition***. FDA-2016-D-2268 (Nov. 6, 2020). Compliance with this regulation is fundamental to the distribution of ibrexafungerp.

59. Defendants professed to have requisite knowledge of these regulations. For example, the Company claimed:

> A drug manufacturing program subject to extensive governmental regulations requires robust quality assurance systems and experienced personnel with the relevant technical and regulatory expertise as well as strong project management skills. ***We believe we have a team that is capable of managing these activities.***

Similarly, on May 12, 2022, the Company's then-CEO Marco Taglietti touted on an earnings call that, at its core, Scynexis was a manufacturing business:

> I would like to remind you that SCYNEXIS at its DNA actually is a manufacturing company. This is what the company has been for probably 2 decades. So we know how to develop, produce, manufacture a product, and the supply chain has been actually quite successfully making sure that the product was available in all pharmacies.

60. Although ibrexfungerp is manufactured by a contract facility, the Company admitted that it was in control of the drugs. For example, on August 14, 2023, the Company admitted that "the Company's product revenue, net comprised of sales of BREXAFEMME that the Company sold as principal given ***it maintains control of BREXAFEMME product until delivery to its wholesalers at which point control is transferred***," and "the Company continues to sell BREXAFEMME in the GSK Territory. The Company is the principal for these transactions under ASC 606 as ***the Company maintains control of the BREXAFEMME inventory that is then sells to its customers***." These statements show that Scynexis is responsible for the integrity of the drugs it sells, underscoring that Defendants must ensure the contract manufacturing facility complied with cGMP.

61. The Individual Defendants were aware of the details of manufacturing of its only drug, for which the Company maintained control of; or if the Company's CEOs and CFOs were unaware, this ignorance constitutes acting in such a

deliberately reckless manner as to constitute a fraud and deceit upon Plaintiff and other Class members.

### B. The New Commercial Partner, GSK, Was Quickly Able To Uncover The Issue, Which Demonstrates The Egregious, Obvious Failure To Comply With cGMP

62. While Scynexis had been manufacturing and selling BREXAFEMME since 2021, GSK was able to uncover within six months that the Company was not complying with cGMP and that a recall was needed.

63. Analysts were perplexed by how such a basic error was allowed to occur, recognizing that "We would expect that ahead of GSK's March licensing agreement it would have physically inspected the IBX manufacturing facilities." As the research analyst firm, Ladenburg Thalmann, explained in a January 3, 2024 report:

> **Looking for clarity**. ***We still lack clarity as to why the manufacturing equipment was shared with beta-lactams and how it was not discovered earlier.*** Recall, Brexafemme earned FDA approval for vulvovaginal yeast infections in June 2021, and we believe its commercial manufacturing is the same as its clinical manufacturer. ***We would expect that ahead of GSK's March licensing agreement it would have physically inspected the IBX manufacturing facilities.*** We look for clarity on this during our meeting with mgt in San Francisco next week, or upon the restart of the MARIO study. However, given GSK's involvement we may not gain the feedback we're accustomed to hearing.

64. Given Defendants' claims they had selected a manufacturer and instituted a team with experience to oversee manufacturing, the only logical

inference is that the Individual Defendants had knowledge of, or were reckless in not knowing, that the manufacturing facility was not complying with appropriate guidelines. The Company and its employees' knowledge or recklessness is even further supported by the fact that GSK was able to uncover these issues.

## VIII. CLASS ACTION ALLEGATIONS

65. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a class, consisting of all persons and entities that purchased or otherwise acquired Scynexis securities between March 31, 2023 and September 22, 2023, inclusive, and who were damaged thereby (the "Class"). Excluded from the Class are Defendants, the officers, and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors, or assigns, and any entity in which Defendants have or had a controlling interest.

66. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Scynexis's shares actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can only be ascertained through appropriate discovery, Plaintiff believes that there are at least hundreds or thousands of members in the proposed Class. Millions of Scynexis shares were traded publicly during the Class Period on the NASDAQ. Record owners and other members of the Class may be identified

from records maintained by Scynexis or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

67. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of here.

68. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation.

69. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

(a) whether the federal securities laws were violated by Defendants' acts as alleged here;

(b) whether statements made by Defendants to the investing public during the Class Period omitted and/or misrepresented material facts about the business, operations, and prospects of Scynexis; and

(c) to what extent the members of the Class have sustained damages and the proper measure of damages.

70. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation makes it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

## IX. UNDISCLOSED ADVERSE FACTS

71. The market for Scynexis's securities was open, well-developed, and efficient at all relevant times. As a result of these materially false and/or misleading statements, and/or failures to disclose, Scynexis's securities traded at artificially inflated prices during the Class Period. Plaintiff and other members of the Class purchased or otherwise acquired Scynexis's securities relying upon the integrity of the market price of the Company's securities and market information relating to Scynexis, and have been damaged thereby.

72. During the Class Period, Defendants materially misled the investing public, thereby inflating the price of Scynexis's securities, by publicly issuing false and/or misleading statements and/or omitting to disclose material facts necessary to make Defendants' statements, as set forth here, not false and/or misleading. The statements and omissions were materially false and/or misleading because they

failed to disclose material adverse information and/or misrepresented the truth about Scynexis's business, operations, and prospects as alleged here.

73. At all relevant times, the material misrepresentations and omissions particularized in this Complaint directly or proximately caused or were a substantial contributing cause of the damages sustained by Plaintiff and other members of the Class. During the Class Period, Defendants made or caused to be made a series of materially false and/or misleading statements about Scynexis. These material misstatements and/or omissions had the cause and effect of creating in the market an unrealistically positive assessment of the Company and its financial well-being and prospects, thus causing the Company's securities to be overvalued and artificially inflated at all relevant times. Defendants' materially false and/or misleading statements during the Class Period resulted in Plaintiff and other members of the Class purchasing the Company's securities at artificially inflated prices, thus causing the damages complained of herein when the truth was revealed.

## X. APPLICABILITY OF PRESUMPTION OF RELIANCE (FRAUD-ON-THE-MARKET DOCTRINE)

74. The market for Scynexis's securities was open, well-developed and efficient at all relevant times. As a result of the materially false and/or misleading statements and/or failures to disclose, Scynexis's securities traded at artificially inflated prices during the Class Period. On April 3, 2023, the Company's share price closed at a Class Period high of $3.67 per share. Plaintiff and other members of the

Class purchased or otherwise acquired the Company's securities relying on the integrity of the market price of Scynexis's securities and market information relating to Scynexis, and have been damaged thereby.

75. During the Class Period, the artificial inflation of Scynexis's shares was caused by the material misrepresentations and/or omissions particularized in this Complaint causing the damages sustained by Plaintiff and other members of the Class. During the Class Period, Defendants made or caused to be made a series of materially false and/or misleading statements about Scynexis's business, prospects, and operations. These material misstatements and/or omissions created an unrealistically positive assessment of Scynexis and its business, operations, and prospects, thus causing the price of the Company's securities to be artificially inflated at all relevant times, and when disclosed, negatively affected the value of the Company shares. Defendants' materially false and/or misleading statements during the Class Period resulted in Plaintiff and other members of the Class purchasing the Company's securities at such artificially inflated prices, and each of them has been damaged as a result.

76. At all relevant times, the market for Scynexis's securities was an efficient market for the reasons below, among others:

(a) Scynexis shares met the requirements for listing, and was listed and actively traded on the NASDAQ, a highly efficient and automated market;

(b) As a regulated issuer, Scynexis filed periodic public reports with the SEC and/or the NASDAQ;

(c) Scynexis regularly communicated with public investors via established market communication mechanisms, including through regular dissemination of press releases on the national circuits of major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; and/or

(d) Scynexis was followed by securities analysts employed by brokerage firms who wrote reports about the Company, and these reports were distributed to the sales force and certain customers of their respective brokerage firms. Each of these reports was publicly available and entered the public marketplace.

77. As a result of the foregoing, the market for Scynexis's securities promptly digested current information regarding Scynexis from all publicly available sources and reflected such information in Scynexis's share price. Under these circumstances, all purchasers of Scynexis's securities during the Class Period suffered similar injury through their purchase of Scynexis's securities at artificially inflated prices and a presumption of reliance applies.

78. A Class-wide presumption of reliance is also appropriate in this action under the Supreme Court's holding in *Affiliated Ute Citizens of Utah v. United*

*States*, 406 U.S. 128 (1972), because the Class's claims are, in large part, grounded on Defendants' material misstatements and/or omissions. Because this action involves Defendants' failure to disclose material adverse information regarding the Company's business operations and financial prospects—information that Defendants were obligated to disclose—positive proof of reliance is not a prerequisite to recovery. All that is necessary is that the facts withheld be material in the sense that a reasonable investor might have considered them important in making investment decisions. Given the importance of the Class Period material misstatements and omissions set forth above, that requirement is satisfied here.

## XI. NO SAFE HARBOR

79. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any allegedly false statements pleaded in this Complaint. The statements alleged to be false and misleading here all relate to then-existing facts and conditions. In addition, to the extent certain of the statements alleged to be false may be characterized as forward looking, they were not identified as "forward-looking statements" when made and there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. In the alternative, to the extent that the statutory safe harbor is determined to apply to any forward-looking statements pleaded herein, Defendants

are liable for those false forward-looking statements because at the time each of those forward-looking statements was made, the speaker had actual knowledge that the forward-looking statement was materially false or misleading, and/or the forward-looking statement was authorized or approved by an executive officer of Scynexis who knew that the statement was false when made.

## XII. CLAIMS FOR RELIEF

### FIRST CLAIM

**Violation of Section 10(b) of The Exchange Act and Rule 10b-5 Promulgated Thereunder Against All Defendants**

80. Plaintiff repeats and re-alleges each and every allegation contained above as if fully set forth herein.

81. During the Class Period, Defendants carried out a plan, scheme and course of conduct which was intended to and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; and (ii) cause Plaintiff and other members of the Class to purchase Scynexis's securities at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each defendant, took the actions set forth here.

82. Defendants (i) employed devices, schemes, and artifices to defraud; (ii) made untrue statements of material fact and/or omitted to state material facts

necessary to make the statements not misleading; and (iii) engaged in acts, practices, and a course of business which operated as a fraud and deceit upon the purchasers of the Company's securities in an effort to maintain artificially high market prices for Scynexis's securities in violation of Section 10(b) of the Exchange Act and Rule 10b-5. All Defendants are sued either as primary participants in the wrongful and illegal conduct charged here or as controlling persons as alleged below.

83. Defendants, individually and in concert, directly and indirectly, by the use, means or instrumentalities of interstate commerce and/or of the mails, engaged and participated in a continuous course of conduct to conceal adverse material information about Scynexis, as specified herein.

84. Defendants employed devices, schemes and artifices to defraud, while in possession of material adverse non-public information and engaged in acts, practices, and a course of conduct as alleged here in an effort to assure investors of Scynexis's value and performance and continued substantial growth, which included making, or the participation in the making of, untrue statements of material facts and/or omitting to state material facts necessary to make the statements made about Scynexis and its business operations and future prospects in light of the circumstances under which they were made, not misleading, as set forth more particularly herein, and engaged in transactions, practices and a course of business

which operated as a fraud and deceit upon the purchasers of the Company's securities during the Class Period.

85. Each of the Individual Defendants' primary liability and controlling person liability arises from the following facts: (i) the Individual Defendants were high-level executives and/or directors at the Company during the Class Period and members of the Company's management team or had control thereof; (ii) each of these defendants, by virtue of their responsibilities and activities as a senior officer and/or director of the Company, was privy to and participated in the creation, development and reporting of the Company's internal budgets, plans, projections and/or reports; (iii) each of these defendants enjoyed significant personal contact and familiarity with the other defendants and was advised of, and had access to, other members of the Company's management team, internal reports and other data and information about the Company at all relevant times; and (iv) each of these defendants was aware of the Company's dissemination of information to the investing public which they knew and/or recklessly disregarded was materially false and misleading.

86. Defendants had actual knowledge of the misrepresentations and/or omissions of material facts set forth here, or acted with reckless disregard for the truth in that they failed to ascertain and to disclose such facts, even though such facts were available to them. Such defendants' material misrepresentations and/or

omissions were done knowingly or recklessly and for the purpose and effect of concealing the truth about Scynexis from the investing public and supporting the artificially inflated price of its securities. As demonstrated by Defendants' overstatements and/or misstatements of the Company's business, operations, financial well-being, and prospects throughout the Class Period, Defendants, if they did not have actual knowledge of the misrepresentations and/or omissions alleged, were reckless in failing to obtain such knowledge by deliberately refraining from taking those steps necessary to discover whether those statements were false or misleading.

87. As a result of the dissemination of materially false and/or misleading information and/or failure to disclose material facts, as set forth above, the market price of Scynexis's securities was artificially inflated during the Class Period. In ignorance of the fact that market prices of the Company's securities were artificially inflated, and relying directly or indirectly on the false and misleading statements made by Defendants, or upon the integrity of the market in which the securities trades, and/or in the absence of material adverse information that was known to or recklessly disregarded by Defendants, but not disclosed in public statements by Defendants during the Class Period, Plaintiff and the other members of the Class acquired Scynexis's securities during the Class Period at artificially high prices and were damaged thereby.

88. At the time of said misrepresentations and/or omissions, Plaintiff and other members of the Class were ignorant of their falsity, and believed them to be true. Had Plaintiff and the other members of the Class and the marketplace known the truth regarding the problems that Scynexis was experiencing, which were not disclosed by Defendants, Plaintiff and other members of the Class would not have purchased or otherwise acquired their Scynexis securities, or, if they had acquired such securities during the Class Period, they would not have done so at the artificially inflated prices which they paid.

89. By virtue of the foregoing, Defendants violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

90. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases and sales of the Company's securities during the Class Period.

## SECOND CLAIM

### Violation of Section 20(a) of The Exchange Act Against the Individual Defendants

91. Plaintiff repeats and re-alleges each and every allegation contained above as if fully set forth here.

92. Individual Defendants acted as controlling persons of Scynexis within the meaning of Section 20(a) of the Exchange Act as alleged. By virtue of their high-

level positions and their ownership and contractual rights, participation in, and/or awareness of the Company's operations and intimate knowledge of the false financial statements filed by the Company with the SEC and disseminated to the investing public, Individual Defendants had the power to influence and control and did influence and control, directly or indirectly, the decision-making of the Company, including the content and dissemination of the various statements which Plaintiff contends are false and misleading. Individual Defendants were provided with or had unlimited access to copies of the Company's reports, press releases, public filings, and other statements alleged by Plaintiff to be misleading prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or cause the statements to be corrected.

93. In particular, Individual Defendants had direct and supervisory involvement in the day-to-day operations of the Company and, therefore, had the power to control or influence the particular transactions giving rise to the securities violations as alleged here, and exercised the same.

94. As set forth above, Scynexis and Individual Defendants each violated Section 10(b) and Rule 10b-5 by their acts and omissions as alleged in this Complaint. By virtue of their position as controlling persons, Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and other members of the Class

suffered damages in connection with their purchases of the Company's securities during the Class Period.

## XIII. PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief and judgment, as follows:

(a) Determining that this action is a proper class action under Rule 23 of the Federal Rules of Civil Procedure;

(b) Awarding compensatory damages in favor of Plaintiff and the other Class members against all defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including interest;

(c) Awarding Plaintiff and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

(d) Any other relief that the Court may deem just and proper.

## XIV. JURY TRIAL DEMANDED

Plaintiff hereby demands a trial by jury.

Dated: September 23, 2024

By: *s/ Donald A. Ecklund*

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